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 COURT  
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5 Attorneys for Plaintiff AIDS HEALTHCARE FOUNDATION

6  
 7 UNITED STATES DISTRICT COURT  
 8 CENTRAL DISTRICT OF CALIFORNIA

9 04-12104

CV04-0216 ABC (MANX)

10 UNITED STATES OF AMERICA ex  
 rel. AIDS HEALTHCARE

11 FOUNDATION,

12 Plaintiffs,

13 vs.

14 SERONO, INC.; DOES 1 TO 50,

15 Defendants

) Case No.:

) FILE UNDER SEAL PURSUANT TO 31  
 ) U.S.C. SECTION 3730(b) (2)

) DO NOT PLACE IN PRESS BOX  
 ) DO NOT PLACE IN PACER

) FALSE CLAIMS ACT COMPLAINT AND  
 ) DEMAND FOR JURY TRIAL

17 1. AIDS Healthcare Foundation (the "relator") brings this  
 18 action on behalf of the United States of America against  
 19 defendants for treble damages and civil penalties arising from  
 20 the defendants' false statements and false claims in violation  
 21 of the Civil False Claims Act, 31 U.S.C. Sections 3729 et seq.  
 22 (the "Act"). The violations arise out of false claims to the  
 23 Medicaid and Medicare programs for the drug Serostim,  
 24 manufactured and marketed by defendant Serono, Inc. ("Serono").  
 25

Complaint

1        2. As required by the Act, the relator has provided to  
2 the Attorney General of the United States and to the United  
3 States Attorney for the Central District of California a  
4 statement of material evidence and information related to the  
5 complaint. Because the statement includes attorney-client  
6 communications and work product of relator's attorneys, and is  
7 submitted to the Attorney General and to the United States  
8 Attorney in their capacity as potential co-counsel in the  
9 litigation, the relator understands this disclosure to be  
10 confidential.

11        3. This action arises under the False Claims Act. This  
12 Court has jurisdiction over this case pursuant to 31 U.S.C.  
13 Sections 3732(a) and 3730(b). This court also has jurisdiction  
14 pursuant to 28 U.S.C. Sections 1331 and 1345.

15        4. Venue is proper pursuant to the Act, 31 U.S.C. Section  
16 3732(a), because the acts prescribed by the Act and complained  
17 of herein took place in this district.

18        5. Relator is a non-profit corporation registered to do  
19 business and doing business in the State of California. Its  
20 non-profit mission is to provide medical treatment and advocacy  
21 to people with HIV/AIDS and their families regardless of ability  
22 to pay. AHF brings this action based on direct, independent  
23 knowledge and also on information and belief.

24        6. AHF is an original source of this information to the  
25 United States. It has direct and independent knowledge of the

Complaint

1 information on which the allegations are based and has  
2 voluntarily provided the information to the Government before  
3 filing an action under the False Claims Act, which is based on  
4 the information.

5 7. The United States of America provides payment for  
6 medical care to qualifying citizens under the Medicaid and  
7 Medicare programs. Medical providers, pharmacists, and  
8 pharmacies, among others, make claims for reimbursement for  
9 services from monies provided in part by the United States under  
10 the Medicaid and Medicare programs. These programs are the

11 primary payors for people with HIV/AIDS in California, if not  
12 the entire country.

13 8. Defendant Serono is a pharmaceutical company. It  
14 manufactures, distributes, and sells a drug called Serostim, and  
15 related products. Upon information and belief, Serostim is a  
16 type of growth hormone. One of the purposes for which Serostim  
17 is used is to combat a syndrome called AIDS wasting, which can  
18 afflict people with HIV/AIDS.

19 9. AHF has a long history criticizing the appropriateness  
20 and use of Serostim for this purpose. AHF has taken the  
21 position that, for people with HIV/AIDS, use of Serostim is  
22 rarely justified or useful. Moreover, given its steep price of  
23 as much as \$6,000.00 per month and negligible effect, the drug  
24 is ripe for fraud, abuse, and black market dealings. Further,  
25 the unnecessary use of the drug limits the amount of Medicaid

Complaint

1 and Medicare funds available for more beneficial medical  
2 treatments for people with HIV/AIDS.

3 10. AHF has worked closely with State and federal  
4 governments to assure appropriate use of Serostim for AIDS  
5 wasting. AHF provided the California Attorney General's office  
6 with declarations for use in litigation surrounding Serostim,  
7 and has met with and provided information to the United States  
8 Department of Justice regarding Serono and Serostim.

9 11. AHF has learned that Serono has engaged in practices  
10 specifically designed to increase the use and prescribing of

11 Serostim to people with HIV/AIDS, even when not medically  
12 appropriate. These practices include but are not limited to:

13 A. Providing pharmacists with a "rebate" in exchange  
14 for providing demographic information for patients  
15 prescribed Serostim, including the identity of the  
16 prescriber of the drug. This allowed Serono to aggressively  
17 market and solicit the prescriber, in order to increase  
18 sales and use of the drug. These "rebates" could be up to  
19 \$300.00 per month per prescription, a fee completely in  
20 excess of the amount of time and effort involved in  
21 providing the data to Serono;

22 B. Employees and/or agents for Serono would provide  
23 guidance to providers on completing paperwork, known as  
24 Treatment Authorization Requests or "TAR's," required for  
25 the Medi-Cal program to pay for Serostim prescriptions for

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1 Medicaid recipients. These employees/agents actually  
2 assisted the providers in filling out the forms, and  
3 instructed them on what terms and items were necessary in  
4 order for the TAR to be approved, and for Medi-Cal to pay  
5 for the prescription.

6 C. As this medication ostensibly was prescribed for  
7 AIDS patients to combat a syndrome known as "AIDS wasting,"  
8 evidence of this wasting needed to be obtained. A primary  
9 method of evidencing wasting is the use of a Bio-impedance  
10 Analysis or "BIA," which measures a person's body mass index

11 (a measurement of fat to muscle). Equipment used to measure  
12 this can cost thousands of dollars, and requires a person  
13 trained in nutrition sciences to properly operate the  
14 equipment to achieve correct results, and properly interpret  
15 the results. Serono piloted a program whereby it offered  
16 free tests of BIA to providers. Persons trained, employed,  
17 and/or working under the auspices of Serono brought these  
18 machines into the offices of providers, performed tests on  
19 patients, recorded and then interpreted the results to the  
20 providers. This is an inherent conflict of interest, and  
21 the accuracy and veracity of any tests performed in such  
22 matter is suspect, as well as any prescription for Serostim  
23 based in part on the result of this tests.

24 12. In essence, Serostim created a complete assembly line  
25 devised to do one thing - manufacture prescriptions for

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1 Serostim. From the information provided by the pharmacies,  
2 Serono could identify and target doctors already predisposed to  
3 prescribe the drug. It then manufactured medical results showing  
4 a need for the drug, and then assisted in writing and completing  
5 documentation so that the prescriptions would be covered by  
6 Medicaid and/or Medicare.

7 13. By engaging in these practices, Serono knowingly  
8 misled the government, and knowingly assisted in misleading the  
9 government, into paying for prescriptions for Serostim that were  
10 not necessary.

11 First Cause of Action

12 (Violation of 31 U.S.C. Section 3729)

13 14. AHF realleges and incorporates the allegation of  
14 paragraphs 1 - 13 as if fully set forth herein.

15 15. By its conduct, Serono caused to be presented to the  
16 United States Government a false or fraudulent claim for payment  
17 or approval.

18 16. By its conduct, Serono knowingly made, used, or caused  
19 to be made or used a false record or statement to get a false or  
20 fraudulent claim paid or approved by the Government.

21 17. Serono combined, conspired, and agreed with other  
22 persons and entities to defraud the United States by assisting  
23 in submitting false claims to the United States and to its  
24 grantees for the purpose of getting the false or fraudulent  
25 claims for prescriptions for Serostim paid or allowed and

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1 committed the other overt acts set forth above in furtherance of  
2 that conspiracy.

3 18. The above conduct is in violation of 31 U.S.C. Section  
4 3729(a), causing damage to the United States.

5  
6 WHEREFORE, AHF respectfully requests the Court to enter  
7 judgment against defendants, as follows:

8 (a) That the U.S. be awarded damages in the amount of three  
9 times the damages sustained by the U.S. because of the  
10 false claims and fraud alleged within this Complaint;

11 (b) That civil penalties of \$11,000.00 be imposed for each  
12 and every false claim that Serono caused to be  
13 presented or assisted in presenting to the U.S. and/or  
14 its grantees;

15 (c) That pre- and post-judgment interest be awarded, along  
16 with reasonable attorneys' fees, costs, and expenses  
17 which AHF necessarily incurred in bringing and pressing  
18 this case;

19 (d) That the Court grant permanent injunctive relief to  
20 prevent any recurrence of the False Claims Act for  
21 which redress is sought in this Complaint;

22 (e) That AHF be awarded the maximum amount allowed to it  
23 pursuant to the False Claims Act; and

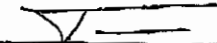
24 (f) That this Court award such other and further relief as  
25 it deems proper.

Complaint

1  
2 DEMAND FOR JURY TRIAL

3 AHF, on behalf of itself and the United States, demands a  
4 jury trial on all claims alleged herein.  
5

6 Dated this 13<sup>th</sup> day of January,  
7 2004

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